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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,522	10/16/2001	Richard A. Descenzo	29520/37890	5026

7590 12/30/2003

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,522

Applicant(s)

DESCENZO ET AL.

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20020506.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-6 and 8-18 in Paper No. 20031001 is acknowledged. The traversal is on the ground(s) that Groups I and V, and Groups III and IV may be searched and examined together. This is not found persuasive because the kit of Group V can be used to detect LOX polynucleotides from sources other than the transgenic plants of Group I; and the methods of Groups II and IV have different starting materials and method steps, and thus each would require a different search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-24 are pending. Claims 7 and 19-24 are withdrawn. Claims 1-6 and 8-19 are examined.

Claim Objections

Claims 11 and 12 are improperly dependent. Claim 11 cannot depend from itself.

Claim Rejections - 35 USC § 112

Claims 1-6 and 8-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a DNA which would hybridize to the non-coding strand of SEQ ID NO: 2 or 4, but for the redundancy of the genetic code.

Applicant describes polynucleotides of SEQ ID NO: 2 and 4 from *Vitis vinifera* encoding LOX polypeptides of SEQ ID NO: 1 and 3 and DNA sequences that would hybridize to SEQ ID NO: 2 or 4 under hybridization conditions of moderate stringency and encode a LOX polypeptide from *Vitis vinifera*.

Applicant does not describe any polynucleotide sequences that would hybridize to SEQ ID NO 2 or 4 under conditions of unspecified stringency, but for the redundancy of the genetic code (i.e. DNA sequences that don't hybridize with SEQ ID NO: 2 or 4 because they have not enough common sequence identity even though they encode a LOX polypeptide from *Vitis vinifera*). It is noted that the sequences of (b) and (c) may be obtained from a LOX polypeptide, but does not necessarily have any activity.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.* At 1406.

Based upon the disclosure of SEQ ID NO: 1, there is insufficient relevant identifying characteristics to allow one skilled in the art to completely determine the structure of polynucleotide sequences that would hybridize to SEQ ID NO: 2 or 4, but for the redundancy of the genetic code, including mutants and allelic variants, absent further guidance. Since the claimed genus encompasses undisclosed or yet to be discovered sequences that hybridize to SEQ ID NO: 2 or 4 and encode a LOX polypeptide from *Vitis vinifera*, the disclosure of SEQ ID NO: 2 and 4 encoding a LOX polypeptide from *Vitis vinifera* does not provide adequate description of the claimed genus. In view of the level of knowledge and skill in the art one skilled in the art would not recognize from Applicant's disclosure that Applicant was in possession of the genus of polynucleotides encoding a LOX polypeptide from *Vitis vinifera*, other than SEQ ID NO: 2 and 4 encoding SEQ ID NO: 1 and 3, that encode a LOX polypeptide from *Vitis vinifera* as broadly claimed.

Given the failure of the structure of polynucleotide sequences that would hybridize to SDEQ ID NO: 2 or 4, but for the redundancy of the genetic code to be adequately described wherein said sequences encode a LOX polypeptide from *Vitis vinifera*, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-1111.

Claims 1-6 and 8-18 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides of SEQ ID NO: 2 and 4 from *Vitis vinifera* encoding LOX polypeptides of SEQ ID NO: 1 and 3, does not reasonably provide enablement for polynucleotide sequences that would hybridize to SEQ ID NO 2 or 4 but for the redundancy of the genetic code (i.e. DNA sequences that don't hybridize with SEQ ID NO: 2 or

Art Unit: 1638

4 because they have not enough common sequence identity even though they encode a LOX polypeptide from *Vitis vinifera*) under conditions of unspecified stringency. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims encompass unspecified substitutions, deletion, additions and combinations thereof. Applicant recited no function or activity for sequences of Claim 1(b) and Claim 1(c), even though these sequences may be obtained from LOX sequences, Applicant does not recite hybridization conditions and provides no guidance as to what changes one of skill in the art could make to the sequence of SEQ ID NO 2 and 4 and still be able to use them.

Claims 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant broadly claims a method for modifying the flavor of a comestible by contact with an unspecified quantity of purified LOX polypeptide of either SEQ ID NO: 1 or 3 from *Vitis vinifera* under non-specified conditions resulting in a non-specified change flavor.

Applicant teaches SEQ ID NO: 2 and 4 from *Vitis vinifera* encoding LOX polypeptides of SEQ ID NO: 2 and 4.

Applicant does not teach a method of using any LOX polypeptide from any source for use in any method for flavor modification of any comestible.

The unpredictability in modifying the flavor of foods is revealed in an attempt to analyze the components that make up the flavor of bread. The unpredictability in flavor modification is in not knowing which components should be promoted or how to synthesize flavor in food (M. Martinez-Anaya, Journal of Agricultural and Food Chemistry, 1996, Vol. 44, No. 9 pages 2469-2480). The authors state that flavor in bread and in other foods are “composed of a large number of components many with very different olfactory components” that “seem to act in a synergistic way” on page 2469; and that the summary of information reveals “complex interactions between flour components, processing conditions, fermenting microflora, and spontaneous and/or exogenous enzymic systems and their repercussions on bread flavor” on page 2478 first column; See Conclusions. The unpredictability would require undue trial and error experimentation to modify flavor of a comestible given the lack of guidance in the specification and the unpredictability in the art.

Given the unpredictability in the art as to which combinations of the components making up the unique flavor in any one of a multitude of comestibles; the breadth of the claims encompassing a method for modifying the flavor of a non-specified comestible by contact with an unspecified quantity of purified LOX polypeptide of either SEQ ID NO: 1 or 3 from *Vitis vinifera* under non-specified conditions resulting in a non-specified change flavor; the lack of guidance in the examples of the specification or in the prior art as to which components of flavor when modified would result in a different flavor; although one of skill in the art can readily add purified LOX enzyme to a food product one would not know based upon Applicant's disclosure which embodiments would be inoperable and predictably eliminated, and thus undue trial and error experimentation would be needed by one skilled in the art to make a comestible with a

Art Unit: 1638

modified flavor and would require one of skill in the art to test a myriad of non-exemplified combinations of flavor components for flavor modification in a multitude of non-exemplified comestibles. Therefore, the invention is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8-10, 13-15, and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1(b), “moderately stringent conditions”, page 9 of the specification gives one example of “moderately stringent conditions”. It is unclear what other conditions would be considered moderate.

Claim 1, part c); “would hybridize” is indefinite. The hybridization language is not a limitation because there are no hybridization conditions recited.

Claim 5 fails to further limit Claim 1.

Claim 17, “modify the flavor characteristics” is indefinite. It is not clear what combination of flavor characteristics and to what degree the “flavor” is to be modified. It is unclear how to determine when flavor has been modified.

All Claims are rejected

Claims 1-6 and 8-18 are deemed free of the prior art, given the failure of the prior art to

teach or reasonably suggest an isolated polynucleotides of SEQ ID NO: 2 and 4 from *Vitis vinifera* encoding polypeptides of SEQ ID NO: 1 or 3 and a method of modifying the flavor of a comestible by adding purified polypeptides of SEQ ID NO: 1 or 3.

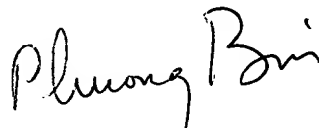
Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
December 20, 2003


PHUONG T. BUI
PRIMARY EXAMINER